

Office Action Summary	Application N .	Applicant(s)	
	09/596,073	BOLOGNA ET AL.	
	Examiner Alton N. Pryor	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-10 and 14-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 6,10 and 14 is/are allowed.
- 6) Claim(s) 1-5,7-9,15 and 16 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - a) All
 - b) Some *
 - c) None of the CERTIFIED copies of the priority documents have been:
 1. received.
 2. received in Application No. (Series Code / Serial Number) _____.
 3. received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

14) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	17) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
15) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	18) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
16) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.	19) <input type="checkbox"/> Other: _____

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DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,3-5,7-9,15,16 are rejected under 35 U.S.C. 102(b) as being anticipated by Bologna et al on record (US 5,543,150; 8/6/96).

Bologna discloses a composition comprising progesterone, cross-linked polycarboxylic acid (polycarbophil), and water soluble polymer (Carbopol 934P). Bologna teaches a method of delivering the composition to a mucosal surface (vaginal cavity). Progressive hydration does not mean that the composition is free of water.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bologna as applied to claims 1,3-5,7-9, 15,16 above in further view of Bologna above.

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Bologna teaches all that is recited in claim 2 except for the composition/method comprising progesterone in about 50% or less. One having ordinary skill in the art would have been expected to determine the optimum amount of progesterone through routine experimentation. One would have been motivated to do this in order to make a composition and to develop a process that would supply progesterone to the vagina.

Claim Objection / Allowable Subject Matter

Claims 6,10,14 are allowable. The prior art does not disclose or suggest the instant composition and method comprising testosterone.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 703 308-4691. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703 305-3592 for regular communications and 703-305-3592 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.



ANP

July 14, 2001